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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,667	10/27/2003	Paul J. Maddon	P0741.70006US00	4456

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1643

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/695,667	Applicant(s) MADDON ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-193 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-193 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed April 26, 2004, is acknowledged and has been entered. Claims 17, 18, 21-24, 26, 31, 50, 54, 62, 71, 74, 77, 79, 91-94, 159, 162, 169, 174, 180, 184, 187, 188, and 190-193 have been amended.
2. Claims 1-193 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-101 and 187-193, drawn to a composition comprising isolated PSMA protein, or a kit comprising said composition, classified, for example, in class 530, subclass 350.

Group II. Claims 102-136, drawn to a method for processing a PSMA protein, or for promoting or preserving dimeric association of PSMA protein in solution, classified, for example, in class 436, subclass 163.

Group III. Claims 137-166, drawn to a method for purifying a sample containing a PSMA protein, classified, for example, in class 436, subclass 161.

Group IV. Claims 167 and 168, drawn to a method for identifying an agent that promotes or preserves dimeric association of PSMA protein, classified, for example, in class 436, subclass 501.

Group V. Claims 169-186, drawn to a method for eliciting or enhancing an immune response in a subject, said method comprising administering to the

subject a composition comprising isolated PSMA protein, classified, for example, in class 424, subclass 277.1.

4. The inventions are distinct, each from the other because of the following reasons:
The inventions of Group I are products, whereas the inventions of Groups II-V are processes.

The inventions of Group I and the inventions of Groups II-IV are unrelated because the products of Group I are not specifically used or otherwise involved in the processes of Groups II-IV.

The inventions of Group I and the inventions of Group V are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the protein can be used in a materially different process of using that product, such as the process of using the protein as a substrate to purify an antibody that binds to the protein by affinity chromatography.

The inventions of Groups I and V have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group I would not suffice to provide adequate information regarding the merit of the claims of Group V, and vice versa, since the searches are not the same, nor are they

one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I and V, an examination of both would constitute a serious burden.

Since the inventions of Groups I and V have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups II-V are unrelated, or are otherwise patentably distinct, each from the other, for the following reasons:

The inventions of Group I are methods for processing a PSMA protein so as to promote or preserve dimeric association of PSMA protein in solution. In contrast, the inventions of Group III are processes for purifying a sample containing a PSMA protein. The inventions of Group IV are processes for identifying an agent that promotes or preserves dimeric association of PSMA protein; and the inventions of Group V are processes for eliciting or enhancing an immune response in a subject comprising administering to the subject a composition comprising isolated PSMA protein.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects. See MPEP §§ 806.04 and 808.01. The instant specification does not appear to disclose that any of the inventions of Groups II-V are useable together. Therefore, because the inventions of Groups II-V have different modes of operation, different functions, and different effects, the inventions appear unrelated.

If not unrelated, the inventions of Groups II-V are patentably distinct, each from the others, for the following reasons:

Again, the inventions of Groups II-V have different purposes or objectives. In addition, the inventions of Groups II-V are materially different processes comprising different process steps. For example, the inventions of Group II are processes for, or involving promoting and/or preserving dimeric association of PSMA protein in solution, whereas the inventions of Group III are processes for purifying a sample containing a PSMA protein, and the inventions of Group V involve administering to patients afflicted

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with a disease or condition treatable by the process. Furthermore, as the inventions of the different groups have different purposes or objectives, they necessarily involve the measurement of different endpoints and/or the establishment of different correlations, and consequently have different criteria for success. For these reasons, any of the inventions of Groups II-V are patentably distinct from the others.

Because any of the inventions of Groups II-V are distinct for these reasons, the search required to examine claims directed to any one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to any other. Furthermore, the inventions of Groups II-V have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter. Because different searches would have to be performed to examine claims directed to any of the inventions of Groups II-V, an examination of more than one would constitute a serious burden.

Since the inventions of Groups II-V have been shown to be patentably distinct, each from the others, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order

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to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
May 25, 2006